

8EHQ-0992-12826

CIBA-GEIGY

## Chemicals Division

CIBA-GEIGY Corporation  
P. O. Box 18300  
Greensboro, North Carolina 27419-8300  
Telephone 919 632 6000

Contains NO CBI

RECEIVED DOCUMENT RECEIPT OF

92 SEP -1 PM 1:41

August 28, 1992

8EHQ-92-12826  
INIT 09/01/92

Document Processing Center (TS-790)  
Office of Toxic Substances  
Environmental Protection Agency  
401 M. Street, SW  
Washington, DC 20460



88920010891

Attention: Section 8(e) Coordinator (CAP Agreement)

RE: 8E CAP - 0024

Dear Section 8(e) Coordinator:

Enclosed are the original and two copies of a study CIBA-GEIGY Corporation is submitting pursuant to the TSCA Section 8(e) Compliance Audit Program and CAP Agreement number 8E CAP-0024. We are submitting the following information, as required by the CAP Agreement:

Company Name: CIBA-GEIGY Corporation  
444 Saw Mill River Road  
Ardsley, New York 10502-2699

Attention: Mr. Anthony Di Battista  
Manager, Regulatory Affairs & Toxic Substances  
Compliance  
Telephone (914) 479-2776

## Tested Chemical:

Thiols, C8-20, gamma-omega -perfluoro, telomers with acrylamide;  
identified as Lodyne K81'84

CAS No.: 70969-47-0

Report Title: Single Dose Oral Toxicity in Rats/Acute Oral LD  
50 in Rats (Project No. MB 85-7641 A, dated 4/17/85)

## Summary:

The test material was administered orally to ten rats (5/sex) at a dose of 5 gm/kg which resulted in mortality in 7/10. Physical signs noted in survivors were piloerection, alopecia and brown staining of the anogenital area, lethargy, ptosis, chromodacryorrhea, chromorhinorrhea, and ataxia. Based on the observation of ataxia in two surviving males observed over 2 to

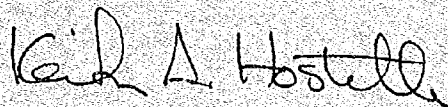
3 days, followed by lethargy, it is concluded that the test material exhibits neurotoxicity potential at high oral doses.

Category: Unit II.B.2.b

Prior Reporting: Not Applicable

Please call the undersigned at (919) 632-7237 if you have any questions about this submittal.

Very Truly Yours,

A handwritten signature in black ink, appearing to read "Keith A. Hostetler". The signature is fluid and cursive, with the first name "Keith" and last name "Hostetler" clearly legible.

Keith A. Hostetler, Ph.D., DABT  
Manager, Hazard Assessment  
Chemicals Division

Enclosures

(2 copies of this letter)  
(3 copies of the study)

cc: A. Di Battista



Codepage 6-8/84

I.D. # 12155-2

# MB Research Laboratories, Inc.

PROJECT NUMBER: MB 85-7641 A

TEST ARTICLE : MA-126, Tox #85-015

SPONSOR : CIBA-GEIGY CORPORATION

TITLE : SINGLE DOSE ORAL TOXICITY IN RATS/ACUTE ORAL LD 50 IN RATS

PROTOCOL # : 31-02 R/A

steinsburg and wentz roads

post office box 178

spinnerstown, pennsylvania 18068

215-536-4110

## ABSTRACT

**Method Synopsis** - Five healthy male and five healthy female albino rats were dosed orally with MA-126 at 5.0 g/kg of body weight. The rats were observed 1, 2 and 4 hours after dosing and daily for 14 days for mortality, toxicity and pharmacological effects. Body weights were recorded pretest, at death and at termination in the survivors. All animals were examined for gross pathology. Although seven animals died at the 5.0 g/kg dose level, a multi-dose LD 50 was not performed per client request.

**Summary** - Three of ten animals survived the 5.0 g/kg oral dose.

Five females and two males died during the study. Predeath physical signs were wetness of the nose/mouth area, lethargy, ptosis, piloerection, brown staining of the anogenital area, ataxia, wetness of the anogenital area, chromodacryorrhea, chromorhinorrhea, dyspnea, few feces, redness of the anogenital area and tachypnea. Necropsy of the deaths revealed abnormalities of the gastrointestinal tract, brown and yellow staining of the anogenital area and red and brown staining of the nose/mouth area.

Physical signs noted in survivors were piloerection, brown staining of the anogenital area, lethargy, alopecia of the anogenital area, ptosis, chromodacryorrhea, chromorhinorrhea, wetness of the nose/mouth area, ataxia, few feces and wetness of the anogenital area.

Body weight increases and necropsy results of survivors were normal.

**Conclusion** - The LD 50 is less than 5.0 g/kg of body weight.

## QUALITY ASSURANCE EVALUATION

The Quality Assurance Unit reviewed various aspects of the raw data and final report on the following dates:

April 9, 1985

April 16, 1985

*Kenneth W. Cerven* 4/17/85  
Kenneth W. Cerven  
Quality Assurance

Respectfully submitted,

*Oscar M. Moreno* 4/16/85  
Oscar M. Moreno, Ph.D.

*Daniel R. Cerven* 4/16/85  
Daniel R. Cerven, Study Director

*Elizabeth J. Altenbach* 4/15/85  
Elizabeth J. Altenbach, Archivist

Submitted: 4/17/85

MD

TITLE OF REPORT

SINGLE DOSE ORAL TOXICITY IN RATS/ACUTE ORAL LD 50 IN RATS

PROTOCOL NUMBER

31-02 R/A

OBJECTIVE

To determine the potential for toxicity of the test article when administered orally. Initially a 5.0 g/kg dose was administered to five male and five female rats. If two or more of the same sex or three of either sex died and the deaths were attributed to test article administration, then an LD 50 was conducted.

TEST ARTICLE

Source and Date  
Received : CIBA-GEIGY CORPORATION 3/06/85  
Label : MA-126, Tox #85-015  
Storage : The test article was stored at ambient room temperature and humidity.  
Description of  
Test Article : Clear Viscous Liquid  
Specific  
Gravity : 1.25  
Sample :  
Preparation : Used as received

TEST ANIMALS

Five male and five female Wistar Albino rats/group were selected for this test from a larger group which had been quarantined at least one week. The animals were received from Ace Animals on 3/12/85.

The pretest body weight range was 204-236 g for males and 196-223 g for females.

Animals were identified by cage notation and indelible body marks.

The animals were housed 5/cage in suspended wire mesh cages. Bedding was placed beneath the cages. Fresh Purina Rat Chow (Diet #5012) was freely available except for 16-20 hours prior to dosing. Water was freely available at all times.

The animal room, reserved exclusively for rats on acute tests, was temperature and humidity controlled, had a 12 hour light/dark cycle and was kept clean and vermin free.



TEST DATES

<u>Dose</u> <u>g/kg</u>	<u>Date Started</u>	<u>Date Ended</u>
5.0	3/20/85	4/03/85

EXPERIMENTAL DESIGN

The test article was administered orally, one time, by syringe and dosing needle at a dose level of 5.0 g/kg. \* If two or more of one sex or three of either sex died, a four dose level screen in two rats was run to determine four dose levels for the LD 50.\* For liquid materials, the dose was based on the sample weight as calculated from the specific gravity. For solids and other semi-solids, the test article was mixed with a vehicle to make dosing by gavage possible. The dose was based on the dry weight of the test article. The dose schedule follows:

<u>GROUP</u>	<u>DOSE</u> <u>g/kg</u>
MA-126	5.0

TYPE AND FREQUENCY OF OBSERVATIONS

In Vivo : Animals were observed 1, 2 and 4 hours post dosing and once daily thereafter for 14 days for mortality, toxicity and pharmacological effects.

Body weights were recorded pretest and at termination.

Post Mortem : All animals were examined for gross pathology.

ANALYSIS OF DATA

If fewer than three rats died, the LD 50 was estimated to be greater than 5.0 g/kg. If additional doses were given, the LD 50 and 95% Confidence were calculated by the method of Litchfield, J.T. Jr., & F. Wilcoxon JPET 96:99, 1949 or Horn H.J. Biometrics 12:311, 1956.

The test article was; 1) not toxic if the LD 50 was greater than 5.0 g/kg; 2) toxic if the LD 50 was less than 5.0 g/kg and greater than 50 mg/kg; 3) highly toxic if the LD 50 was less than 50 mg/kg.

### RETENTION OF DATA

The raw data is filed at MB Research by MB project number. The final report is filed at MB Research by sponsor name and MB project number.

The test article will be retained for six months from date of this report.

### REVISION OF THE PROTOCOL

A multi-dose LD 50 was not performed, as per client request.

### RESULTS

#### 1. LD 50:

The LD 50 is less than 5.0 g/kg of body weight.

2. <u>MORTALITY:</u>	Dose Level g/kg	# Treated M/F	# Dead M/F	Day of Death (M/F)			
				0	1	4	6
	5.0	5/5	2/5	0/1	0/4	1/0	1/0

#### 3. BODY WEIGHTS AND DOSE VOLUME:

An. # & Sex	Dose Volume cc	Day 0 g	Day 14 g
1-M	0.84	210	DEAD DAY 6*
2-M	0.94	236	342
3-M	0.87	217	DEAD DAY 4 (158 g)
4-M	0.82	204	291
5-M	0.88	221	316
MEAN		217.6	316.3
S.D.		12.2	25.5
6-F	0.87	218	DEAD DAY 1 (205 g)
7-F	0.89	223	DEAD DAY 0
8-F	0.84	210	DEAD DAY 1 (204 g)
9-F	0.88	220	DEAD DAY 1 (211 g)
10-F	0.78	196	DEAD DAY 1 (188 g)
MEAN		213.4	----
S.D.		10.9	----

\*animal was cannibalized; therefore, terminal body weight was not recorded



@ 5.0 g/kg

T O X I C I T Y

MB RESEARCH LABS  
PROJECT: MB 85-7641 A  
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AN. # & SEX	H O U R				D A Y														PAGE	- 5 -
	1	2	4		1	2	3	4	5	6	7	8	9	10	11	12	13	14		
1-M	1	1			BQEF MJ	QBFEJ S2X	QMEFB12	BF2	FBNJ2	Z(cannibalized)										
2-M	1	1	BQ		SUBQF	SUBQF E24X	FB2	FB2	FB2	F26	F26	F					F	F		
3-M	1	BQE1	BQEF1		SBQEF	SUBQF E24X	FBSJ2	Z										F		
4-M	1	12	2		SBQEFJ	SUBQE F24X	FSB2	FB2	FBJ2	FJ26	F26	FQ6	FQ6	F6	F6	F6	F6	F		
5-M	1	1			SBQF	SUBQE F24X	FSEB2	BF2	BF2	F2	F	F6	F6	F6	F6	F6	F6	F		
6-F	E1	QB14	QB14		Z													F		
7-F	1	Q1	BQ14Z																	
8-F	1	12	BQ124		Z															
9-F	1	B12	B5Q24		Z															
10-F	1	13	BQF134		Z															

AT ALL TIMES NOT MENTIONED, ALL ANIMALS APPEARED NORMAL.

- CODE: B = lethargy  
E = ataxia  
F = piloerection  
J = chromodacryorrhea  
M = dyspnea  
Q = ptosis  
S = chromorhinorrhea  
Z = dead  
X = few feces
- 1 = nose/mouth wet  
2 = anogenital area stained brown  
3 = anogenital area stained red  
4 = anogenital area wet  
6 = alopecia at anogenital area

MB RESEARCH LABS  
PROJECT: MB 85-7641 A  
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NECROPSY OBSERVATIONS

Ø 5.0 g/kg:	1-M	2-M	3-M	4-M	5-M	6-F	7-F	8-F	9-F	10-F
	<u>D</u>	<u>S</u>	<u>D</u>	<u>S</u>	<u>S</u>	<u>D</u>	<u>D</u>	<u>D</u>	<u>D</u>	<u>D</u>
Normal										
Cannibalized										
Nose/mouth stained red										
Nose/mouth stained brown										
Anogenital area stained brown										
Anogenital area stained yellow										
Stomach, red										
Stomach distended with dark brown fluid										
Stomach distended with gas										
Intestines, red										
Intestines distended with mucus										
Intestines distended by clear fluid										
Intestines distended by dark mucus										

CODE: D = death  
S = sacrifice  
1 = slight or scattered  
2 = moderate or few  
3 = pronounced or many  
X = observed



## AIR RESEARCH LABORATORIES

## STUDY TITLE:

SINGLE DOSE ORAL TOXICITY/LD 50 IN RATS

PROTOCOL NO:  
31-02 8/12

SAMPLE: MH-126, 70x 85-015

DT, REC'D: 3/6/55

LOC: B

SAMPLE DESC: Oral Toxicity

PH: 11-25

PROJECT NO: 85-7641-A

UAR/ AMT.  
DT: USED: AMT.

SAMPLE PREPARATION(S) - IF REQUIRED:

BY: DT: TM:

SPONSOR: CIBA

STUDY DIR:

TEST

START: 3/26/55

TEST

END: 3/26/55

DOSING:

NEEDLE:

PROTOCOL SYNOPSIS: USE SM &amp; SF M/A RATS/Grp. HOUSE 5/sex/Cg. PRETEST BODY WT.

RANGE: Males 200-250; Females 180-230g. DOSE @ 5.0 g/kg. OBSERVE 1, 2 &amp; 4 hrs postdose &amp; x day for 14 days. BODY WTS Pre, death &amp; @ term in survivors.

NECROPSY ALL.

LD 50: If 2 or more ans of same sex die, or if 3 ans of either sex die @ 5.0 g/kg, DOSE 4 add'l grps based on results of screen. If 5.0 g/kg level is nec. for calc. of LD 50, it will be repeated. DOSE ALL LD 50 LEVELS SIMULTANEOUSLY.

Screen: DOSE 4 grps of 2 rats/grp. One level must be 0.5 g/kg. NO NECROPSY.

## COMMENTS:

LD 50:

## FOOTNOTES:

1- Nec/mouth <sup>wet</sup> brown 3/26/55  
 2- Nec/know 3/26/55  
 3- Nec/2x 3/26/55  
 4- Nec/wet 3/26/55  
 6- Nec/2x 3/26/55

## QUALITY ASSURANCE:

STY INSPECTED: DATE INIT

RAW DATA AUDITED: 1/1/55

FINAL REPT ADT'D: 4/16/55

A - ANIMAL  
 B - BATTERY  
 C - CLIMATE  
 D - DIARRHEA  
 E - ATAXIA  
 F - PULSATION  
 G - PROSTRATE  
 H - CUMULATIVE  
 I - CONVULSION  
 J - CHROMATOPHYLLIN  
 K - NEGATIVE REACTION  
 L - REFLEX  
 M - DISPERSED  
 N - TACTILE  
 O - TACTILE  
 P - SPASM  
 Q - PROCTIC  
 R - ALBERTA  
 S - CHROMATOPHYLLIN  
 T - TACTILE  
 U - TACTILE  
 V - YELLOW URINAL DISCHARGE  
 W - ABDOMEN PLOATED  
 X - APPARENT IMITATED  
 Y - FEW LIGES  
 Z - YELLOW URINAL DISCHARGE

DEPT. O. MOOREHEAD  
 DEPT. J. L. SMITHSON  
 DEPT. D. CIPRIAN  
 DEPT. R. CRAWFORD  
 DEPT. A. RALPH  
 DEPT. B. ALLENBACH  
 DEPT. J. J. JACOB  
 DEPT. S. WEATHERBY  
 DEPT. A. RALPH  
 DEPT. B. ALLENBACH  
 DEPT. J. J. JACOB  
 DEPT. S. WEATHERBY

SAMPLE:

M1A 126

SPONSOR:

C184

STUDY TITLE:

SDOT/LD 50

PROJECT #:

85-7641 A

PROTOCOL #:

31-02

MBR

DOSE: 5C, 1KG BY: 8/2 DT: 3/20 TM: 9:30

DOSE VOLUME:

4.00 M/KG

VIA: GAVAGE: ✓

DIET:

SUPPLY/

REC'D:

RM/

SEXED

FASTED:

TM: 4:00BY: 8/2

## OBSERVATIONS

(\*) / = SEE CAGE TRANS. FORM

AN.#	VOL	BODY WT - G	DAY 0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
SEX	CC		1 HR	2 HR	4 HR												
#1 M		0	14														
#2 M																	
#3 M																	
#4 M																	
#5 M																	
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DATE:

3/20

TIME:

9:30

INITI:

KAL

VERIF:

KAL



TEST ARTICLE: 11/1/81		SACRIFICE AGENT: <i>Conrad, S. Z. 11/1/81</i>				
DATE OF DEATH	3/21	3/21	3/21	3/21	3/21	3/21
TEST DAY	1	1	1	1	1	1
SACRIFICE(S)/DEATH(D)	D	D	D	D	D	D
DOSE G/KG	51					
ANIMAL NUMBER/SEX	1	2	3	4	5	6
NORMAL						
CANNIBALIZED						
Nose/mouth stained red					2	
Nose/mouth stained brown			1		1	1
AGA stained red						
AGA stained brown			3			
AGA yellow				3	1	2
Lungs: Congestion						
Lungs: Hemorrhage						
Heart dilated						
Pericarditis						
Pleural cav.-excess fluid						
Liver Nodule(s)						
Liver abscess(es)						
Kidney(s) hydronephrotic						
Stomach red				3	2	3
Stomach distended <i>fluid</i>				3	3	3
<i>Intest. w/ fluid</i>			2			
Intestines red				3	3	3
Intestines distended-mucus			2			
Intestine distended <i>by clear fluid</i>				3	3	3
" " <i>dist. mucus</i>					2	1
Peritoneal cav.-excess fluid						
1=slight or scattered 2=moderate or few 3=pronounced or many ✓ = observed						
DATE NECROPSIED:	3/24	3/24	3/24	3/24	3/24	3/24
NECROPSIED BY:	W	W	W	W	W	W
VERIFIED BY:						

B 01

06/11/92

COLORS

COMPONENT LANGUAGE INFO

GCLFN960

Action Code: (A,C,D)

Comp-Num: 02584

Lang Code: ENG

Cas-Num: 70969-47-0

Oshapel Desc: NOT ESTABLISHED

Iarc Desc: NOT LISTED

Acgih-Tlv Desc: NOT ESTABLISHED

Ntp Desc: NOT LISTED

TSCA Status: T (T=TSCA,R=R&D,E=Pesticide,F=FDA,P=PMN,N=unk,I=Impure,D=Descr)

Idl: CEPA: D (D=DSL, R=NSN,L=NDSL,T=Transitional list, N=not on list )

Type Ssd Translation

Page: 01

CM FLOUOROCHEMICAL NONIONIC SURFACTANT

CN Thiols, C8-20, .gamma.-.omega.-perfluoro, telomers with acrylamide

CP LODYNE K8184 A.I.

Next Selection:



B 02

PERCENTAGE -> 100.15

06/12/92

COLORS

COMPONENT SCROLL MAINTENANCE

Page 01

GCLFN963

Language ENG

Product 309005100 001 LODYNE K8184 30%

Component

ACTIVE COLORANT

CODE E=Pesticide, F=FDA, P=PMN, TSCA Status T=TSCA, R=R&D  
I=Impur, D=Descrp

S	Nbr	Description	Cas No	TS	Percent	O	Sh	Sn	Rn
-	02508	BUTYL CARBITOL	112-34-5	T	32.00	B	N	Y	N
-	01828	WATER	7732-18-5	T	30.00	N	N	Y	N
-	02584	LODYNE K8184 A.I.	70969-47-0	T	30.00	N	N	Y	N
-	02509	N-PROPANOL	71-23-8	T	8.00	O	Y	N	N
-	02510	ACRYLAMIDE	79-06-1	T <	0.10	N	N	N	N
-	00003	ACETIC ACID	64-19-7	T	0.05	N	N	N	N

Next Selection: History Info, Create 06 12 92 Revise 03 17 92 by FAIRFRI963